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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,887	11/13/2003	Jacqueline E. Heard	MBI-0058CIP	5720

47550 7590 09/10/2008

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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
09/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,887	HEARD ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 11 June 2008.

2. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

4. Applicants' response concerning support for the claimed subject matter in a prior filed application has been considered in full (page 5 of the Remarks). The Examiner has reviewed the disclosure of U.S. Provisional Application 60/125,814, filed March 23, 1999, and does not fine adequate written description for instant SEQ ID NO: 3 or 4, or the claimed phenotype of the claimed transgenic plant (instant claim 58, for example). Hence, as previously stated in the last Office action, the priority for the instant claims is given the filing date of U. S. Provisional Application 60/336,049 filed 19 November 2001 (see SEQ ID NO: 185 and 186).

Claim Rejections - 35 USC § 112

5. Claims 57-59, 62-64 and 67-70 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claim a transgenic plant with greater tolerance to osmotic stress, salt and/or water deprivation comprising a recombinant polynucleotide encoding a polypeptide that is at least 85% identical to SEQ ID NO: 4.

Applicants describe a transgenic plant with greater tolerance to osmotic stress, salt and/or water deprivation comprising a recombinant polynucleotide encoding a polypeptide comprising SEQ ID NO: 4.

Applicants do not describe the genus of claimed transgenic plants with greater tolerance to osmotic stress, salt and/or water deprivation comprising a recombinant polynucleotide encoding a polypeptide that is at least 85% identical to SEQ ID NO: 4. In fact, Applicants describe no other species of polypeptide that is at least 85% identical to SEQ ID NO: 4.

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed.

Response to Applicants' arguments concerning the Written Description rejection of the previously presented, presently cancelled claims. Said arguments filed 11 June 2008.

Applicants argue that they have describe how "A polypeptide sequence variant may have "conservative" changes, wherein a substituted amino acid has similar structural or chemical properties" on page 18, lines 4-6. Applicants argue that Table 4 on pages 64-65 list conservative substitutions that might be made "when it is desired to maintain the activity of the protein" (page 64, lines 20-21). Applicants argue that page 64, lines 4-6: "other conservative variations that alter one, or a few amino acids in the

encoded polypeptide, can be made without altering the function of the polypeptide, these conservative variants are, likewise, a feature of the invention" (page 10, 4th paragraph of the Remarks). Applicants argue that "Guidance in determining which and how many amino acid residues may be substituted, inserted or deleted without abolishing functional or biological activity may be found using computer programs well known in the art, for example, DNASTAR software" (page 18, lines 17-20), and "Substitutions that are less conservative than those in Table 5 can be selected by picking residues that differ more significantly in their effect on maintaining (a) the structure of the polypeptide backbone in the area of the substitution, for example, as a sheet or helical conformation" (page 66, lines 3-5). Applicants argue that "The mutations that are made in the polynucleotide encoding the transcription factor should not place the sequence out of reading frame and should not create complementary regions that could produce secondary mRNA structure. Applicants argue that the polypeptide encoded by the DNA performs the desired function" (page 64, lines 14-18) (paragraph spanning pages 10-11 of the Remarks).

These arguments are not found to be persuasive. Applicants describe no variants of instant SEQ ID NO: 4 have the equivalent function in a transgenic plant, and the instant claims recite no conserved structure that produces such an equivalent function. In addition, the use of a computer program would only provide the vast number of variants that would fall within the claimed genus; it would not describe what the specific function of such variants would be.

6. Claims 52-54, 57-64 and 67-70 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a water deprivation tolerant transgenic plant comprising a recombinant polynucleotide that encodes SEQ ID NO: 4, does not reasonably provide enablement for a water deprivation tolerant transgenic plant comprising a recombinant polynucleotide that hybridizes to the complement of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The sequence taught by Applicants, SEQ ID NO: 4, is a GRAS type transcription factor (see page 29 of the instant application). The number of polynucleotides within the scope of the instant claims is vastly greater and not limited to any specific function (instant claims 52-54, 57, 60 and 61. Tolerance to the recited water deprivation types, drought, salt or sucrose, is controlled by many different physiological pathways. Hence, given the limited guidance by Applicants, the nature of the invention, the breadth of the claims and the quantity of experimentation that would be necessary, it would have required undue trial and error experimentation by one of skill in the instant art at the time of Applicants' invention to make and use as broadly claimed.

Response to Applicants' arguments concerning the Written Description rejection of the previously presented, presently cancelled claims. Said arguments filed 11 June 2008.

Applicants argue that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided though broad terminology or

illustrative examples (*In re. Marzocchi,* 439 F2d 220, 223, 169 USPQ 367, 369 (CCPA 1971)). . Applicants argue that it is a matter of routine to use bioinformatics-based analysis to find SCR sequences related to SEQ ID NO: 4 that have a minimum percentage identity to a defined subsequence, then transform plants with the sequences and test the plants in order to find operable species. Applicants argue that once found, the presence of SCR conserved domains are putative indicators of function. Applicants argue that it is a matter of routine to clone sequences identified on the basis of having the claimed conserved domains into nucleic acid constructs, transform and then test plants using routine assays. Applicants argue that the artisan could rely on art-recognized methods to perform these tasks and specifically could use methods provided in the specification (page 6, 4th paragraph of the Remarks).

Applicants argue that the pending Office action analysis also fails to take into account the fact that proteins can be mutated to a significant degree and at multiple sites and maintain a biological function. Applicants argue that the pending Office action analysis fails to take into account that, in addition to the art-recognized methods that may be used to produce the claimed plants, the specification provides extensive guidance for screening sequences, lists functional species, lists species predicted to function, and describes how to: (1) find sequences with SCR conserved domains with a specified degree of homology with similar subsequences in SEQ ID NO: 4; (2) calculate the percent identity between the second conserved domain of SEQ 1D NOs: 4 and the newfound sequence; and, as necessary, (3) test the newfound sequence to determine if it functions as is presently claimed. Applicants argue that guidance for performing these

steps is provided, the methods are well known, and functional species are disclosed. Applicants argue that ample guidance is therefore provided to allow one of skill in the art to identify additional functional sequences. Applicants argue that the amount of experimentation necessary and the amount of guidance presented in the specification are sufficient to allow the skilled artisan to practice the methods and make the plants set forth in the claims (page 7, 2nd paragraph of the Remarks).

Applicants argue that the exemplary claim 73 (referring to the Precedential Opinion of Appeal No. 2007-0819, Application 09/667,859 (decided May 31, 2007) before the Board of Patent Appeals and Interferences) is similar to the instant claims in that a specific percent identity to a region of a sequence is being claimed, albeit a lower percentage identity than that which is instantly claimed (page 7, last paragraph of the Remarks).

Applicants argue that at the time Appellants' application was filed, the level of skill in the relevant art (molecular biology) was high. Applicants argue that methods of making the claimed sequences and screening for activity were known in the art and described in the exemplary and the instant specification (page 8, 6th paragraph of the Remarks).

Applicants argue that similar to the exemplary application, the experimentation involved to produce other sequences within the scope of the claims" and thus to practice the full scope of the claims, would have been well within the skill of those in the art and thus would have been routine (page 8, 7th paragraph of the Remarks).

Applicants' arguments have been fully considered but are not found to be persuasive. Instant claims 52-54, 57, 60 and 61 are directed to transgenic plants having a myriad of undefined phenotypes, which Applicants fail to teach one of skill in the art how to use. The guidance in *Ex parte Kubin* is not completely analogous to in the instant claims because the claim(s) in *Ex parte Kubin* were directed to a polypeptide that specifically bound a specific ligand. In the instant case the encoded polypeptide confers to the transgenic plant greater tolerance to osmotic stress, salt and/or water deprivation as compared to a control plant. One of skill in the instant art would readily recognize that the function of a transcription factor and the function of a ligand binding protein are not analogous as a transcription factor that binds to regulatory regions of a promoter; a ligand binding protein is functionally distinct from a transcription factor. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.".

Claim Rejections - 35 USC § 103

7. Claims 52-70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pysh *et al* (1999, The Plant Journal 18(1): 111-119). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 December 2007. Applicant's arguments filed 11 June 2008, page 12, have been fully considered but they are not persuasive.

Applicants argue that they believe that they conceived and constructively reduced to practice the claimed plants overexpressing G922, SEQ ID NO: 3 and 4, prior to the publication of the Pysh reference in provisional application 60/125,814. This argument is not found to be persuasive. Provisional application 60/125,814 only discloses a partial polypeptide sequence, which in fact is shorter than that taught by Pysh.

Applicants argue that the sequence taught by Pysh is the same sequence as is found in the presently amended claims, since Pysh fails to teach a full length sequence that corresponds to SEQ ID NO: 4. Applicants argue that the reference cited in the Office action does not expressly anticipate or make obvious all of the elements of the claimed invention. As this instant rejection is not made under 35 USC 102, anticipation is not relevant.

Applicants argue that there is no teaching of transgenic plants in the Pysh reference, nor is there a motivation to produce transgenic plants in said reference. Applicants argue that mere disclosure of a sequence is insufficient grounds for establishing a *prima facie* case for obviousness. Applicants argue that if that reasoning

were to be held as a standard, the mere publication of a plant genome would preclude an inventor from obtaining any gene-based patent. This argument is not found to be persuasive. KSR forecloses the argument that a **specific** teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, -- USPQ2d --, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). In the instant case, it would have been obvious to one of ordinary skill in the instant art to isolate the complete coding region and transform a plant, especially using a constitutive or a root-specific promoter. In fact, one of ordinary skill in the instant art would have readily recognized that this would have been the next obvious step using the teachings of Pysh *et al*.

8. Claims 52-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benfey *et al* (WO 97/41152).

Benfey *et al* teach a recombinant polynucleotide encoding amino acids 158-482 of instant SEQ ID NO: 4, in *SCARECROW-LIKE* 3 (*SRPa1* gene, Figure 9A and SEQ ID NO: 21). Benfey *et al* teach a plant transformed with said recombinant polynucleotide at claim 20. Benfey *et al* teach said transformed plant wherein the recombinant polynucleotide is expressed in roots at claim 23. While Benfey *et al* do not specifically teach overexpression of said polynucleotide confers to the transgenic plant greater tolerance to osmotic stress, salt and/or water deprivation, Benfey *et al* do teach that overexpression of said polynucleotide would result in thicker root development (claim 18).

Benfey *et al* do not teach a polynucleotide or plant transformed therewith encoding instant SEQ ID NO: 4.

It would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicants' invention to use the teachings of Benfey *et al* to isolate the complete *SCL3* transgene and transform a plant therewith. The use of a *SCL3* transgene to modify root architecture in a transgenic plant would have been obvious to one of ordinary skill in the instant art. At the time of Applicants' invention, one of ordinary skill in the art would have had a reasonable expectation of success in isolating the complete *SCL3* transgene and produce a transgenic plant therewith. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention).

Conclusion

9. This Office action is non-final in view of the new ground of rejection.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
8 September 2008